



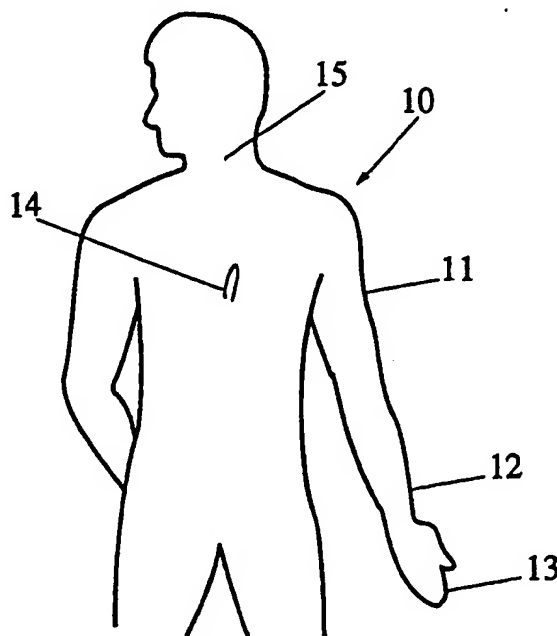
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/AU96/00340</p> <p>(22) International Filing Date: 5 June 1996 (05.06.96)</p> <p>(30) Priority Data: PN 3383 5 June 1995 (05.06.95) AU</p> <p>(71) Applicant (for all designated States except US): PWV MEDICAL PTY. LTD. [AU/AU]; 31 Hope Street, Ermington, NSW 2115 (AU).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): O'ROURKE, Michael, Francis [AU/AU]; 59 Woodwich Road, Hunters Hill, NSW 2110 (AU).</p> <p>(74) Agent: WATERMARK; Level 4, Amory Gardens, 2 Cavill Avenue, Ashfield, NSW 2131 (AU).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>	

(54) Title: IMPROVED CALIBRATION FOR BLOOD PRESSURE PULSES

(57) Abstract

Disclosed is an improved arrangement for allowing more accurate automatic calibration for a system in which blood pressure pulses are derived for remote sites from a calibrated measurement and a waveform measurement, when these are made at different sites. Where a calibrated measurement is made, say, at the brachial artery (11), and a waveform recorded at the radial artery (12), a waveform is derived for the calibrated site using a known transfer function, this derived waveform is then calibrated by the measurements already made, and the calibrated waveform for any remote site, for example the ascending aorta (14), can be derived using a known transfer function.



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IMPROVED CALIBRATION FOR BLOOD PRESSURE PULSES**Technical Field**

The present invention relates to the measurement of peripheral blood pressure pulse waveforms and the use of these waveforms to determine pulse waveforms at other sites. More particular, it is concerned with the calibration of these waveforms.

Background Art

A technique for utilising peripheral pressure pulses to determine the pulse waveform at other body sites, particularly the ascending aortic waveform, is disclosed in U.S. Patent No. 5265011 by Michael F. O'Rourke. The books "The Arterial Pulse" by O'Rourke, Kelly and Avolio published by Lea Febiger, Philadelphia USA 1992 and "Arterial Vasodilation", by O'Rourke, Saffer, and Dzau, published by Arnold, London 1993 disclose the use of a measured peripheral waveform to determine the waveform at another site, using an empirically determined transfer function. The derived waveform can be calibrated, as it is derived from the peripheral waveform which itself is calibrated. In these documents, it is assumed that the brachial cuff sphygmomanometer measurement can be used to directly calibrate waveforms measured at the radial artery. It is assumed that relatively little change occurs in the parameters between the brachial artery and the radial artery. Whilst this is a reasonable working assumption, it is not strictly accurate.

It is an object of the present invention to provide an improved calibration procedure, such that derived waveforms are able to be more accurately calibrated.

Summary of Invention

According to a first aspect, the present invention provides a method of calibrating a derived pressure pulse waveform, said derived waveform being determined by processing a peripherally measured waveform, comprising the steps of:

1. measuring at a first site a blood pressure pulse waveform;
2. measuring substantially simultaneously using a calibrated instrument the systolic and diastolic pressures at a second site;

3. determining the pulse waveform shape at said second site from the waveform measured at said first site using a first predetermined transfer function;

4. calibrating the waveform at said second site using the measured
5 systolic and diastolic pressures;

5. determining the pulse waveform shape at a third site directly or indirectly from the waveform measured at said first site using a second predetermined transfer function;

6. calibrating the waveform at said third site directly or indirectly from
10 the calibrated waveform from said second site, using a third predetermined transfer function.

Preferably, the measurements at the first and second sites are performed non-invasively. The first site may be, conveniently, the radial artery or the finger, and the second site may be the brachial artery, although any convenient site
15 may be chosen.

It will be appreciated that the present invention is not limited to the steps being performed in the particular order shown above. The three different transfer functions mentioned above may in fact be only two different transfer functions, depending upon how the calculation is desired to be performed. The user is only
20 required, in any case, to measure the waveform, and make a calibration measurement. For example, the measured waveform at the first site may be used to derive an uncalibrated waveform at the second site, which is then calibrated by measurement at that site. The calibrated waveform may then be used to calibrate the waveform at the first site. From the calibrated second site waveform,
25 a calibrated waveform at the third site can be directly obtained by applying the appropriate waveform.

It will be understood that the calculation process may be actually be performed in a number of equivalent ways. However, the general principle of the present invention is retained - that is, that a measurement at one site is used to
30 provide calibration for the derived waveform, and at a second site a waveform is acquired for calculating the derived waveform, with different transfer function being used between the first and second sites to the point where the derived

waveform is required.

The measurement steps may be performed with manually operated instruments, and the output data processed by any suitable processor, or the waveform may be measured continuously and calibrated periodically or in real time, either manually or automatically.

This approach allows for a convenient waveform measurement site to be used, which may be not reliable or convenient in terms of accuracy of calibrated pressure measurements, with calibration performed at a convenient site for calibrated measurement.

10 **Brief Description of Drawings**

The present invention will now be described with reference to the accompanying figures, in which:

Figure 1 is a schematic diagram illustrating the sites where measured and derived pressures are located;

15 Figure 2 is a flow chart illustrating the determination of the remote site pressure waveform;

Figure 3 is an illustration showing typical pressure waveforms for the ascending aorta, brachial artery and radial artery; and

20 Figure 4 is a graph showing the transfer functions between the brachial artery and the ascending aorta, and between the radial artery and the ascending aorta.

Description of Embodiment

It will be appreciated that while the present invention is described with reference to particular sites for pressure measurement and for which pressures are derived, the inventive principle is equally applicable to other sites. Moreover, whilst the use of non-invasive techniques is presently preferred for practical reasons, the present invention contemplates the use of an invasively derived waveform or calibration if available or desired. The inventive method may be incorporated in software in any suitable digital processing device, of the type disclosed in the references cited above, as would be readily understood by those skilled in the art.

Referring to figure 1, this is a schematic illustration of the pressure

measurement sites used according to the following discussion. Three sites are of relevance to this discussion on person 10. The site for which the calibrated pressure waveform is required is illustratively the ascending aorta 14. It will be appreciated that according to the present invention this could be any other site for which suitable transfer functions have been derived, for example, the carotid artery 15. The calibrated measurement may be derived by conventional sphygmomanometry at the brachial artery 11. The waveform may be acquired for the purposes of this example at the radial artery 12 - however, it will be appreciated that other sites may be used, for example the finger 13, or carotid artery 15. An uncalibrated waveform may even be acquired at the site for which a calibrated waveform is required, if this is accessible to the pressure measurement instrument.

The waveform may be acquired using any suitable means - for example, a tonometer, or at the finger using the FINIPRES device, or by an in-dwelling pressure catheter. Such devices are widely available commercially, and the reader will be familiar with their operation. The process of acquiring a waveform using a tonometer is described in the O'Rourke et al references cited above. Similarly, the general principles of deriving a waveform for the ascending aorta using transfer functions, and the techniques for deriving such transfer functions, are described in those documents, which are hereby incorporated by reference. Various transfer functions have been published in the scientific literature, which could be adopted for use in the present invention. It will be appreciated that the transfer functions may be derived on a different basis, if desired.

Figure 2 illustrates the process according to the present invention. The waveform is measured at, for example, the radial artery, and the known transfer function used to derive the shape of the waveform at the ascending aorta. A suitable transfer function is shown in figure 4 between each of the brachial and radial artery, and the ascending aorta. Figure 3 illustrates typical pressure waveforms at the radial artery, brachial artery and ascending aorta.

At the same time, or shortly before or after, conventional sphygmomanometry may be used to measure the systolic and diastolic pressures at a suitable site, for example at the brachial artery. The transfer

function defines a relationship between the relative waveform magnitudes at the different sites related by the function. From the radial artery waveform, a transfer function can be used to derive an uncalibrated waveform at the brachial artery, which can then be calibrated using the measured systolic and diastolic pressures at that site. The ascending aorta waveform can then be calibrated from the relative magnitude of the waveforms at the ascending aorta and the brachial artery, and the known calibration at the brachial artery. Accordingly, the derived ascending aorta pressure waveform can be calibrated. It will be appreciated that the processing using transfer functions is conveniently carried out using the Fourier transform of the waveforms, using a suitably programmed microprocessor.

It will be appreciated that an alternative calculation process could be used. For example, the transfer function between the brachial artery and the radial artery could be used to determine a calibrated radial pressure waveform, and the transfer function to the ascending aorta used to determine the calibrated ascending aorta waveform from the radial waveform.

Another alternative would be to use a transfer function from the calibrated brachial artery waveform to derive the calibrated ascending aorta pressure waveform using the appropriate transfer function. The calculation could also be performed in real time, subject to a suitable processor and software being employed, as would be apparent to those skilled in the art. The basic technique remains the same.

It will be appreciated that the present technique allows for a calibrated waveform to be derived for any selected site, from a waveform measured at a different site, provided the corresponding transfer function is known.

The reader will appreciate that variations and additions are possible within the spirit and scope of the invention, within the general inventive concept.

CLAIMS

1. A method of calibrating a derived pressure pulse waveform, said derived waveform being determined by processing a peripherally measured waveform, comprising the steps of:

1. measuring at a first site a blood pressure pulse waveform;
2. measuring substantially simultaneously using a calibrated instrument the systolic and diastolic pressures at a second site;
3. determining the pulse waveform shape at said second site from the waveform measured at said first site using a first predetermined transfer function;
4. calibrating the pulse waveform shape at said second site using the measured systolic and diastolic pressures to provide a calibrated waveform;
5. determining the pulse waveform shape at a third site directly or indirectly from the waveform measured at said first site using a second predetermined transfer function;
6. calibrating the waveform at said third site directly or indirectly from the calibrated waveform from said second site,
so that a calibrated waveform is derived for said third site.

2. A method according to claim 1, wherein the calibrated waveform at said third site is derived directly by applying said second transfer function to the calibrated waveform at said second site.

3. A method according to claim 1, wherein step 5 is performed by calibrating the measured waveform at said first site from the calibrated waveform at said second site, and deriving said third site waveform by applying a said second transfer function from said calibrated waveform at said first site to said third site.

4. A method according to any one of the preceding claims, wherein the first site is selected from the group comprising the radial artery and the finger, and the second site is the brachial artery.

5. A method according to any one of the preceding claims, wherein steps 3 to 6 are performed by software.
6. A method according to claim 1, wherein the first or second site is the same as the third site.

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Fig 1.

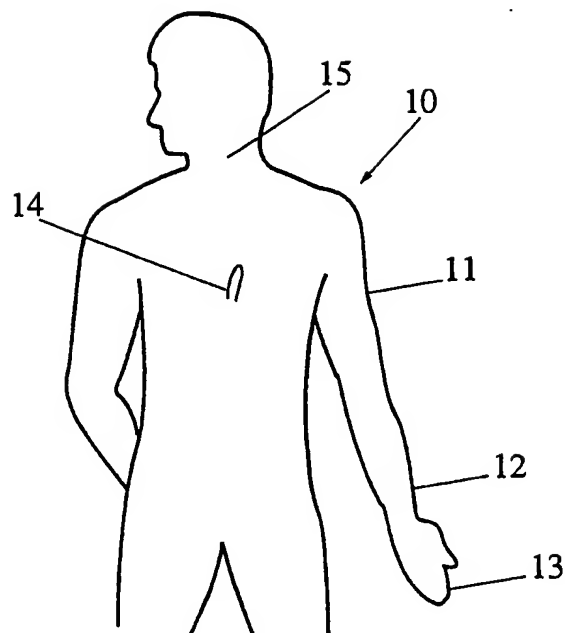
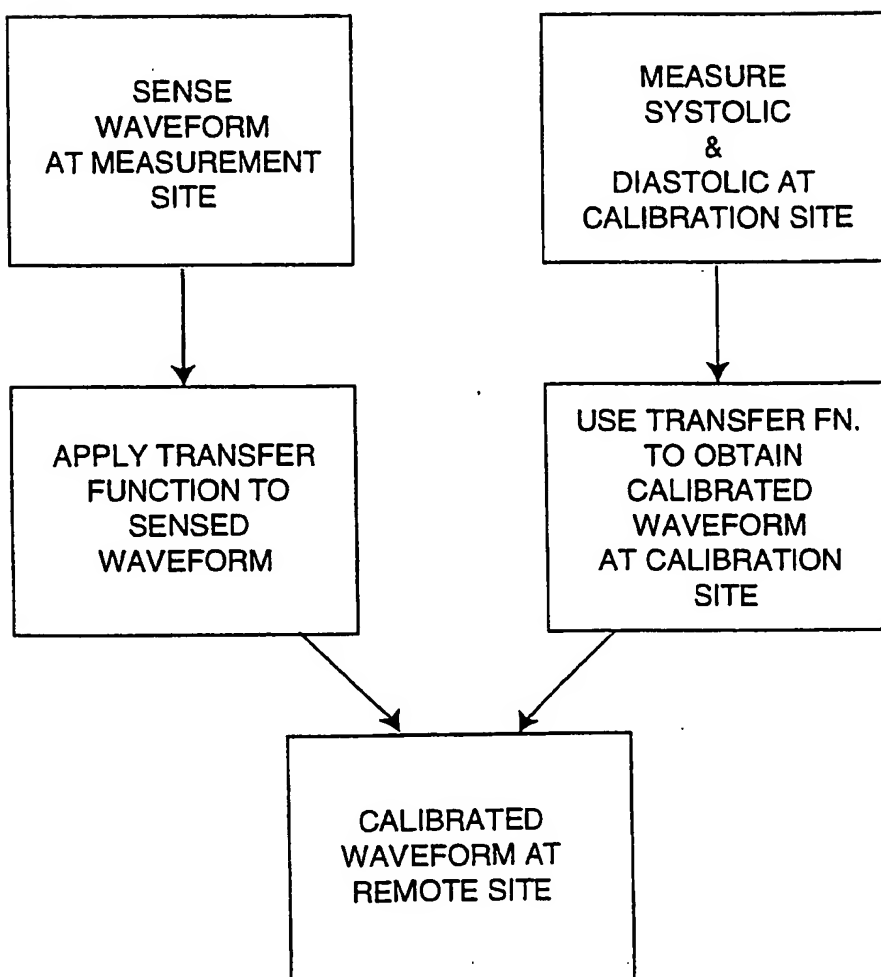


Fig 2.



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Fig 3.

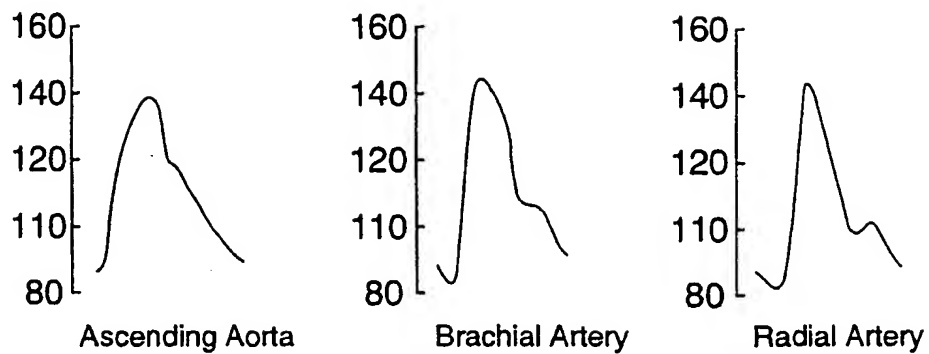
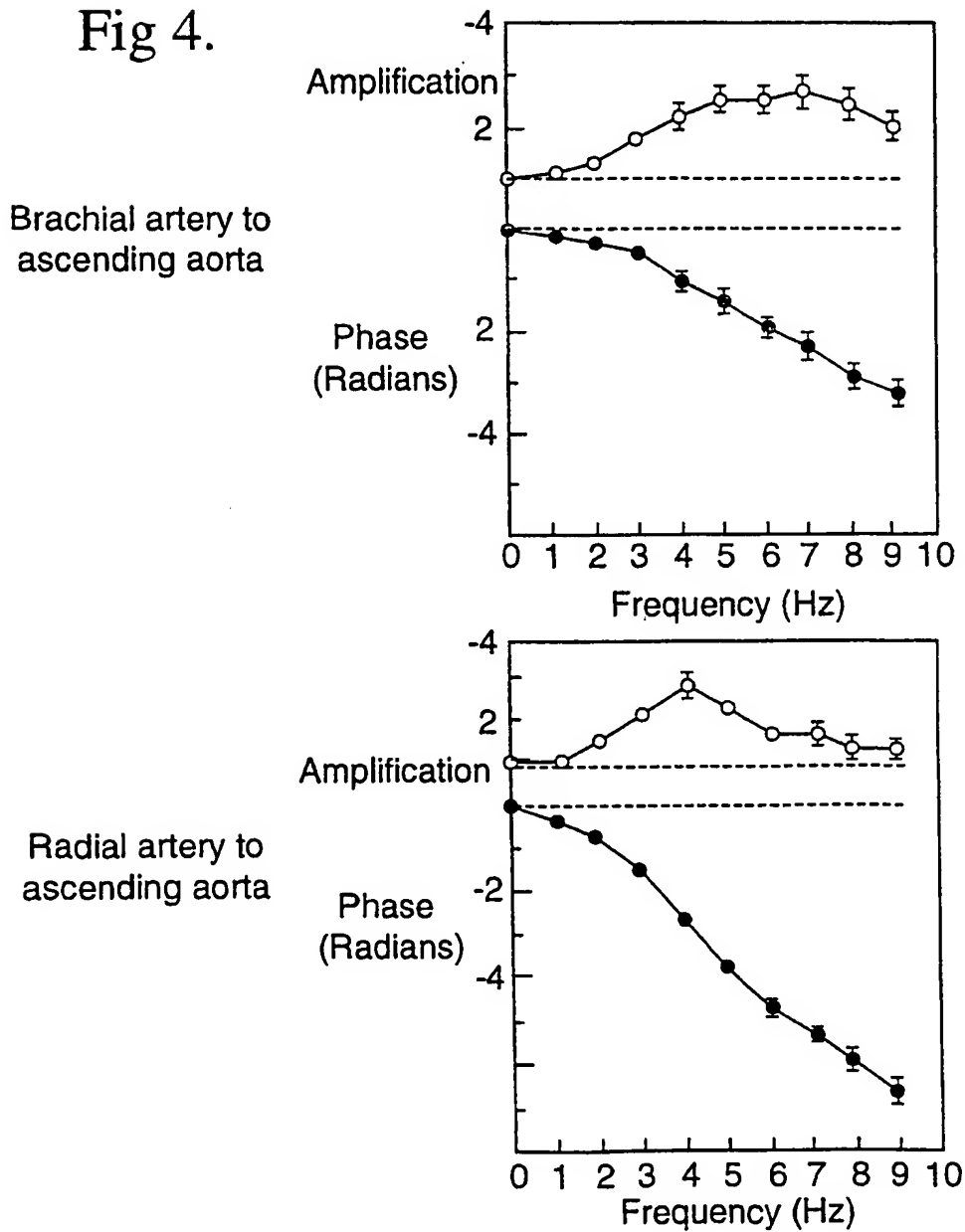


Fig 4.



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 96/00340

A. CLASSIFICATION OF SUBJECT MATTER																						
Int Cl ⁶ : A61B 5/021																						
According to International Patent Classification (IPC) or to both national classification and IPC																						
B. FIELDS SEARCHED																						
Minimum documentation searched (classification system followed by classification symbols) Int Cl ⁶ : A61B 5/02, 5/021																						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: as above																						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT, JAPIO: pressure AND wave: AND calibrat:																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
P, A	AU 15250/95 A (VITAL INSITE INC.) 19 July 1995 whole document																					
A	AU 53556/90 A (EASTERN MEDICAL TESTING SERVICES, INC.) 4 October 1990 whole document																					
A	US 5101828 A (WELKOWITZ, CAI & QI) 7 April 1992 whole document																					
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex																						
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E"</td> <td>earlier document but published on or after the international filing date</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>"&"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E"	earlier document but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family	"P"	document published prior to the international filing date but later than the priority date claimed		
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Date of the actual completion of the international search 6 September 1996		Date of mailing of the international search report 12 SEPT 1996																				
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C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4873987 A (DJORDJEVICH & IVANKOVICH) 17 October 1989 whole document	
A	EP 0 297 146 A (NIPPON-COLIN CO., LTD) 4 January 1989 whole document	

INTERNATIONAL SEARCH REPORT**Information on patent family members**

International Application No.

PCT/AU 96/00340

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
AU	15250/95	US	5533511	WO	9518564
WO	9011043	AU	53556/90	US	5265011
US	5101828	NONE			
US	4873987	CA	1333096	EP	389579
				WO	9000029
WO	8804910	CA	1331788	EP	297146
				US	5099853
END OF ANNEX					